IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ABBOTT LABORATORIES,	)	
	)	
	)	
Plaintiff,	)	Case No. 05 C 6561
v.	)	
	)	Judge Virginia M. Kendall
MYLAN PHARMACEUTICALS, INC.,	)	
	)	
Defendant.	)	
	)	

MEMORANDUM OPINION AND ORDER

Plaintiff Abbott Laboratories ("Abbott") has brought suit against Defendant Mylan Pharmaceuticals, Inc., ("Mylan") for alleged infringement of two patents used in the manufacture of the pharmaceutical "Depakote." Mylan has filed several counterclaims, two of which allege that Abbott's procurement and enforcement of the patents constitute federal antitrust violations. Abbott moves to dismiss these two counterclaims pursuant to Federal Rule of Civil Procedure 12(b)(6). Because Mylan has adequately stated a claim for *Walker Process* fraud, Abbott's Motion to Dismiss is denied.

Facts

For purposes of a motion to dismiss, the Plaintiff's version of the facts of the case is taken as true. In the late 1980's and early 1990's, Abbott procured a number of patents from the United States Patent and Trademark Office ("PTO") in connection with production of the drug Depakote. Abbott has sued Mylan for infringement of two of these patents, Nos. 4,988,731 ("the '731 patent") and 5,212,326 ("the '326 patent").[1] Mylan counterclaims that during the prosecution of these two

[1]The facts underlying Mylan's Complaint have been summarized in this Court's June 13, 2006 Memorandum Opinion and Order.

patents, two individual employees of Abbott made misrepresentations to the PTO that were material to Abbott's procurement of the patents.

Specifically, Mylan alleges that Abbott employee Dr. Bauer submitted a declaration to the PTO during prosecution of the '731 and the '326 patents in which he testified that he had prepared certain compounds or "ionic oligomers" in accordance with the process detailed in the patent, and then tested the compounds. Dr. Bauer testified to the weight and structure of the compounds based on the results of the tests he performed. But Mylan alleges that the tests performed were known to be incapable of measuring the type of oligomer detailed in the patents and that Dr. Bauer could not have reached the conclusions to which he testified on the basis of the tests he performed. Mylan alleges that Dr. Bauer mislead the PTO by suggesting that his tests supported his conclusions and by failing to disclose that the tests he performed were inappropriate for the compounds that he tested. Mylan alleges that Dr. Lambert's declaration corroborated Dr. Bauer's testimony and that a person of Dr. Lambert's skill in the relevant art would have known that the tests were inappropriate and the results inaccurate.

Mylan also alleges that Dr. Bauer's and Dr. Lambert's misrepresentations before the PTO were material to the PTO's decision to grant Abbott the patents. The PTO examiner rejected the continuation-in-part applications for the '731 and the '326 because they were not supported by the specification of the originally-filed application as required by 35 U.S.C. § 112. The Patent Appeals Board reversed the examiner's decision and stated in its opinion that it based its decision to reverse on the declarations of Drs. Bauer and Lambert.

Finally, Mylan alleges that as a result of the fraudulent procurement of the '731 and '326 patents, Mylan has not been able to enter the market for generic Depakote and has been subject to suit by Abbott.

Legal Standard

A motion to dismiss pursuant to Federal Rule of Civil Procedure ("Rule") 12(b)(6) tests the legal sufficiency of the claims alleged in the complaint. *See Cler v. Illinois Educ. Ass'n.*, 423 F.3d 726, 729 (7th Cir. 2005). A complaint will not be dismissed for failure to state a claim unless there is no set of circumstances that could be proved that would entitle the plaintiff to relief. *See Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984); *DeWalt v. Carter*, 224 F.3d 607, 612 (7th Cir. 2000). But a plaintiff may plead facts that show that he has no claim, meriting dismissal. *See McCready v. Ebay*, 453 F.3d 882, 888 (7th Cir. 2006).

Immunity from Antitrust Suit

Generally, a patentee suing to enforce statutory rights is immune from suit for antitrust violations even if the suit has an anticompetitive effect. *See Glass Equip. Dev., Inc.. v Besten, Inc.*, 174 F.3d 1337, 1343 (Fed. Cir. 1999). A patentee who brings suit for patent infringement may be subject to antitrust liability if the alleged infringer can prove either: (i) that the infringement suit was "sham litigation" designed to interfere with legitimate business relationships; or (ii) that the patent was obtained through knowing and willful fraud, known as "*Walker Process*" fraud. *See Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068 (Fed. Cir. 1998); *citing Walker Process Equip., Inc. v. Food Machinery & Chem. Corp.*, 382 U.S. 172, 177 (1965). Sham litigation and *Walker Process* are independent legal theories; if the elements of *Walker Process* liability have been met, liability can be imposed without the additional requirements for sham litigation. *See*

Nobelpharma, 141 F.3d at 1071. Because antitrust actions against patentees are almost always brought as counterclaims to a patent infringement action, Federal Circuit precedent governs determination of whether the patentee's conduct constitutes an antitrust violation. *Id.* at 1067-68.

Abbott argues that Mylan's Third and Fourth Counterclaims as alleged do not fall within either of these exceptions to immunity. Because Mylan has properly pled a claim for *Walker Process* fraud, and because any similarity between this litigation and prior litigation between Abbott and other generic manufacturers is a factual issue for discovery, Mylan's Third and Fourth Counterclaims of *Walker Process* fraud will not be dismissed. Because existence of prior successful litigation to enforce these patents as well as Mylan's own answers to the Complaint and allegations in the Counterclaims foreclose allegations that Mylan's suit is a sham, Mylan may not proceed on a sham litigation theory.

1. Walker Process Fraud

In order to succeed on a claim of *Walker Process* fraud and defeat immunity, an antitrust plaintiff must show: (1) that the patentee obtained the patent through knowing and willful misrepresentation of facts to the PTO; (2) that the patentee was aware of the fraud at the time it brought suit; (3) independent evidence of the patentee's deceptive intent toward the PTO; (4) that the PTO relied upon the misrepresentation, such that it would not have issued the patent but for the misrepresentation. *See C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1364 (Fed. Cir. 1998); *accord Unitherm Food Sys. v. Swift-Eckrich, Inc.*, 375 F.3d 1341, 1358 (Fed. Cir. 2004), *rev'd in part on other grounds*, 126 S.Ct. 980 (2006). Additionally, as discussed in the following section, a plaintiff who demonstrates the elements of fraud must independently allege antitrust injury.

Walker Process claims are fraud claims and are subject to the heightened pleading requirements of Rule 9(b). *See Medimmune, Inc. v. Genentech, Inc.*, 427 F.3d 958, 967 (Fed. Cir. 2005), *rev'd on other grounds*, 549 U.S. – (2007). In order to plead a *Walker Process* claim in accordance with Rule 9(b), Mylan must identify "with particularity the reference or group of references that, but for their omission from [Abbott's] patent applications, the PTO would not have granted the applications." *Netflix Inc. v. Blockbuster, Inc.*, 2006 WL 2458717 (N.D. Cal. Aug. 22, 2006).

At this early stage in the litigation, Mylan has pleaded sufficiently the elements of a *Walker Process* claim. Mylan specifically alleges that Abbott presented two declarations to the PTO that relied upon scientific methods that were known at the time to be inappropriate for testing the specific compounds in Abbott's material. Mylan also specifically alleges, with citation to the proceedings before the Patent Board of Appeals, that but for the declarations containing the misrepresentations Abbott's '731 and '326 patents would not have been approved. While Mylan generally avers Abbott's intent to defraud the PTO, it does not do so in isolation; rather, Mylan supports the inference of intent with the specific actions before the PTO and specific allegations of the state of the art at the time of the actions supporting intent to defraud. Abbott relies heavily upon a prior determination by another court in this district that Abbott's conduct before the PTO did not constitute inequitable conduct. *See Abbott v. Torpharm*, 309 F. Supp. 2d 1043 (N. D. Ill. 2004). Mylan was not a party to that litigation. While the Court may take judicial notice of the existence of such litigation, the Court may not take the facts stated in that opinion to be true for application to a different plaintiff. *See GE Capital Corp. v. Lease Resolution Corp.*, 128 F.3d 1074, 1083 (7th Cir. 1997) (finding that a court "cannot achieve through judicial notice what it cannot achieve

through collateral estoppel" when the plaintiff in a subsequent action was not a party to the previous action and "has never been afforded an opportunity to present its evidence and arguments on the claim").

Abbott will have an opportunity at summary judgment to offer to this Court the same evidence as it offered before the court in *Torpharm*; for purposes of a motion to dismiss, however, the Court takes Mylan's well-pleaded allegations as true and therefore denies the motion to dismiss the claims.

2. Sham Litigation

"In order to prove that a suit was within [the] "sham" exception to immunity, an antitrust plaintiff must prove that the suit was both *objectively* baseless and *subjectively* motivated by a desire to impose collateral, anti-competitive injury." *Nobelpharma*, 141 F.3d at 1071, *citing Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc. ("PRE")*, 508 U.S. 49, 60 (1993). To invoke the 'sham' exception the claimant must show "some abuse of process" and show "more than a failed legal theory." *C.R. Bard*, 157 F.3d at 1368 (internal citations omitted). If an antitrust defendant had probable cause to institute proceedings, requiring only "a reasonable belief that there is a chance that a claim may be held valid upon adjudication," the antitrust defendant cannot be found to have engaged in sham litigation. *See PRE*, 508 U.S. at 62-63.

As discussed above, Abbott has been sued for antitrust violations concerning the '731 and '326 patents previously by other generic drug manufacturers. *See, e.g., Torpharm*, 309 F. Supp. 2d 1043 (and previous opinions in same litigation); *Abbott v. Alra*, 1997 WL 667796 (N.D. Ill. 1997). Both these proceedings ultimately resolved in Abbott's favor and found the patents valid. "A winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore not a

sham." *PRE*, 508 U.S. at 61 n.5; *accord In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 517 (E.D.N.Y. 2005) (relying on evidence of successful prior litigation against other competitors to enforce same patent in finding no evidence of sham litigation).

Additionally, the conduct precipitating Abbott's patent infringement suit, admitted by Mylan, was Mylan's decision to file an Abbreviated New Drug Application ("ANDA") in which Mylan specifically challenged the validity, enforceability, and/or scope of Mylan's '731 and '326 Patents. *See* Answer at ¶¶ 15-17. On the basis of the prior litigation upholding the same patents, and on the basis of Mylan's own averments in its Answer and Counterclaims, Mylan cannot proceed on a sham litigation theory.

Antitrust Injury

In the alternative, Abbott argues that even if the pleading requirements for an antitrust violation have been satisfied, Mylan lacks standing to bring these antitrust claims against Abbott because Mylan cannot allege antitrust injury. While Federal Circuit law governs antitrust suits arising out of a patentee's conduct in enforcing its patent, the Federal Circuit continues "to apply the law of the appropriate regional circuit to issues involving other elements of antitrust law such as relevant market, market power, damages, etc." *Nobelpharma*, 141 F.3d at 1068. To establish antitrust injury, an antitrust plaintiff must show that "claimed injuries are of the type the antitrust laws were intended to prevent and reflect the anti-competitive effect of either the violation or of anticompetitive acts made possible by the violation." *Kochert v. Greater Lafayette Health Services, Inc.* 463 F.3d 710, 716 (7th Cir. 2006) *quoting Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977).

By the terms of the Hatch-Waxman Act, an infringement action by a patentee against an ANDA Paragraph IV filer tolls the effectiveness of an approved ANDA to allow for resolution of the suit. *See* 21 U.S.C. § 355(j)(5)(B)(iii) (describing the moratorium on effectiveness of a generic application pending resolution of infringement suit based on the application). A patentee has only a limited period in which to commence suit after infringement action after an ANDA has been filed; the period in which to commence suit starts from the date of ANDA filing, not ANDA approval. *See id.*[2] Taking Mylan's allegations of fraudulent conduct before the PTO as true for purposes of this motion, using the regulatory advantage afforded via a fraudulently-procured patent to prevent Mylan's entrance into the relevant market is the type of anti-competitive effect that the antitrust laws were designed to prevent.

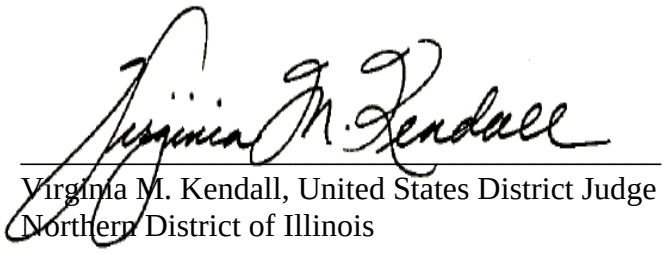
Mylan has adequately alleged that it is prepared to enter the market for generic Depakote but for Abbott's actions in fraudulently procuring the patents. While Abbott makes clear its belief that Mylan cannot carry its burden to demonstrate injury, "a prediction that the plaintiff will be unable to meet its challenges is not a good reason to dismiss a complaint under Rule 12(b)(6)." *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 372 F.3d 899, 902 (7th Cir. 2004) (denying patentee's motion to dismiss counterclaim of generic manufacturer for failure to allege injury). Mylan's Third and Fourth Counterclaims will not be dismissed for failure to allege antitrust injury.

[2]As discussed in detail in *Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 90 F. Supp. 2d 540 (D.N.J. 2000), the structure of these statutes means that, if antitrust injury were tied to the status of FDA approval relative to the required timing of the suit, antitrust injury would be "wholly contingent on the vagaries of timing of agency action" and go against the purpose of the Hatch-Waxman Act. *Id.* at 545. If the FDA approved the ANDA before the patentee filed its motion to dismiss the antitrust counterclaim, then antitrust injury would exist; but if the FDA took too long to complete the approval process, the generic company would be unable to establish injury to support its antitrust counterclaim.

Finally, both parties have referenced minor differences between the Answer and Counterclaims filed before this Court and the Answer and Counterclaims filed in a related action that was transferred to this district. To cure these differences, Mylan has leave to amend its Answer and Counterclaims to include the information in the related action that was not in the document filed in the action before this Court.

Conclusion

Because Mylan has adequately pleaded the elements of an antitrust counterclaim on the basis of *Walker-Process* fraud, Abbott's Motion to Dismiss Mylan's Third and Fourth Counterclaims is denied. The Court grants Mylan leave to file an Amended Answer and Counterclaims to consolidate the papers from prior related actions.



Virginia M. Kendall, United States District Judge
Northern District of Illinois

Date: February 23, 2007